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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1612

NOTIFICATION DATE	DELIVERY MODE
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02/19/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/827,484	Applicant(s) GORE, MAKARAND	
	Examiner Gollamudi S. Kishore, Ph.D	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,3-13,15-20 and 63-67 is/are pending in the application.
4a) Of the above claim(s) 6 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-16 and 63-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The RCE dated 11-14-08 is acknowledged.

Claims included in the prosecution are 1, 3-5, 7-13, 15-16 and 63-67.

In view of the amendment to the claims, the 112 rejections are withdrawn.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 3-5, 7-8, 13, 15 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsu (5,653,996).

Instant claims recite a jettable solution of plurality of vesicles and a pharmaceutical payload encapsulated within each of said vesicles and an edible outer medium with an intended use limitation that the material is jettable with an inkjet dispenser.

Hsu discloses liposomal formulations containing phosphatidylcholines and phosphatidylglycerol in a buffer solution. The active agents include both water soluble and water insoluble active agents. The compositions further contain a surfactant, Tween which is considered as a solvent besides aqueous medium which is necessary for the formation of a liposome structure (abstract, col. 4, line 52 through col. 6, line 35, col. 9,

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lines 28-35, examples and claims). The apparatus in Hsu produces both multilamellar and unilamellar liposomes. Although Hsu does not specifically teach the viscosity of the compositions, since instant claim 12 only recites that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Hsu possess the claimed viscosity. The intended use has no significance in composition claims. Applicant's arguments have been fully considered, but are not persuasive. As pointed out above, lipophilic (water insoluble) active agents sequester in both layers of the lipophilic phospholipids making up the bilayered liposomes in Hsu. Instant claim language 'comprising' does not exclude the lipophilic active agent sequestering also in the outermost layer of the bilayer. Since Hsu teaches water soluble active agents, they sequester within the aqueous core of the liposomes in Hsu reading on the second interpretation of the claim. The reference still reads on instant claims.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues the following:

As would be known of to one of skill in the art, and as explained in Applicant's specification, at paragraph 0049 and elsewhere, in order to be jettable, a composition must have characteristics that will allow it to be delivered given the pressures, temperatures and other parameters of an inkjet material dispenser while protecting the pharmaceutical payload. For example, for a solution to be "jettable" it must have a certain viscosity, surface tension, density, and T-cycle stability. (See e.g., Applicant's specification, paragraphs 0049, 0059). Whether or not the claimed solution is "jettable" is of immense significance. Specifically, as described in Applicant's specification, The precise metering capability of the inkjet material dispenser (150) along with the ability to selectively emit the metered quantity of aqueous vesicle pharmaceutical (160) onto precise, digitally addressed locations makes the present system and method well suited for a number of pharmaceutical delivery applications. According to one exemplary

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embodiment, the precision and addressable dispensing provided by the present inkjet material dispenser (150) allows for one or more compositions to be dispensed on a single edible structure (170). According to this exemplary embodiment, a combination therapy may be produced in a customized dosage for a patient. (Applicant's specification, paragraph 0054). Thus, with the claimed jettable composition, a prescribing physician can order "a customized dosage for a patient" that is then produced by a pharmacist with an inkjet material dispenser, similar to an inkjet printer. (Id.). Without, the jettable solution of Applicant's invention, producing a customized dosage for each patient would be unreasonably expensive. (Applicant's specification, paragraph 0059). Consequently, the patient may have to ingest a much larger, standardized dosage of a pharmaceutical than the patient actually needs. In contrast to the claimed subject matter, none of the cited prior art references teach or suggest the claimed "jettable solution." Specifically, none of the cited references teach or suggest the claimed combination of a pharmaceutical payload encapsulated within each of a plurality of vesicles; and an edible liquid vehicle in which the vesicles are stably dispersed, "wherein said jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload." This subject matter and its advantages are entirely outside the scope and content of the cited prior art. "A claim is anticipated [under 35 U.S.C. § 102] only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131. Therefore, for at least the reasons explained here, the rejection of Applicant's claims based on any of Hsu, Schlossmann, Waldrep and Wallach should be reconsidered and withdrawn. Claim 7 recites: A jettable solution comprising: a plurality of vesicles; and a pharmaceutical payload encapsulated within a central interior of each of said vesicles; wherein said plurality of vesicles each comprise an outer membrane comprised of two layers of molecules and wherein additional pharmaceutical payload is entrapped between said two layers of molecules of said vesicle outer membrane; wherein said jettable solution is jettable with an inkjet material dispenser to deliver a specified dosage of said vesicles encapsulating said pharmaceutical payload. Claim 7 should be considered allowable for at least the same reasons given above in favor of claim 1. Moreover, the final Office Action fails to specifically address claim 7 or to indicate how or where the cited

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prior art teaches the specific subject matter of claim 7. For at least these reasons, the rejection of claim 7 should be reconsidered and withdrawn. Claim 16 was rejected under 35 U.S.C. § 103(a) over any one of Hsu, Schlossmann or Waldrep taken individually. For at least the following reasons, this rejection cannot be sustained. Claim 16 recites: The jettable solution of claim 1, further comprising: approximately 25 % vehicle; approximately 2 % vesicle forming component; approximately 3 to 6 % pharmaceutical payload; and water. As already demonstrated above, the composition and "jettability" of the claimed solution are significant to the advantages obtained by Applicant's discovery".

These arguments are not persuasive. Paragraph 0049 pointed out by applicant states the following:

"[0049] Once the aqueous vesicle pharmaceutical has been satisfactorily formed, it will exhibit a number of desirable properties. According to one exemplary embodiment, the formed aqueous vesicle pharmaceutical will be suitable for inkjet printing from an inkjet material dispenser (150; Fig. 1). According to this exemplary embodiment, the resulting aqueous vesicle pharmaceutical has a viscosity that is no more than approximately 5 centipoise, although the value may be outside of this range. In addition, the surface tension of the final composition is typically between about 25 to about 60 dynes per centimeter, and more preferably between about 35 to about 50 dynes per centimeter."

According to applicant's own definition that the viscosity can be outside 5 centipoise and the surface tension of the composition is recited as a broad range. Hsu's liposomes are suspended either in a buffer or water and applicant has not shown that Hsu's preparations do not have the same viscosity and surface tension. Claims are given the broadest reasonable interpretation and it is still the examiner's position that Hsu's preparations are jettable and applicant has not shown that be otherwise.

6. Claims 1, 3-5 and 7-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Schlossmann (4,976,964).

Schlossmann discloses liposomal dispersions of Nifedipine and dihydropyridines. The phospholipids include phosphatidylcholine and phosphatidylserine. The

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formulations include glycerol (solvent) and buffers. The sizes of the liposomes are 50-100 nm (Col. 3, lines 20-51 and examples). Although Schlossmann does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Schlossmann possess the claimed viscosity. The intended use has no significance in composition claims.

7. Claims 1, 3, 5, 7-8, 12-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Waldrep (5,958,378).

Waldrep discloses liposomal formulations containing cyclosporin. The phospholipids include phosphatidylcholine (abstract, col. 5, lines 25-36, Examples and claims). Although Waldrep does not specifically teach the viscosity of the compositions, since instant claims only recite that the viscosity be less than 5 centipoise, it is the examiner's position, in the absence of showing otherwise, that the compositions of Waldrep possess the claimed viscosity. The intended use has no significance in composition claims.

Applicant provides no specific arguments for this rejection. As pointed out above, instant claims can be interpreted in two ways and the reference of Waldrep still reads on instant claims.

8. Claims 1, 3-5, 7-8, 10-12, 15 and 63-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallach (5,160,669).

Wallach discloses paucilamellar vesicles containing the insecticide within the central cavity (abstract, col. 1, examples and claims). Wallach discloses further mineral

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oil which is a humectant (Table 2). The reference meets the requirements of instant claims.

Applicant's arguments to the above 102 rejections have been fully considered, but are not persuasive. Applicant's arguments are similar to those raised for the rejection of claims over Hsu and therefore, the same response is deemed applicable.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-3, 8, 10-15 and 67 are rejected under 35 U.S.C. 102(a) as being anticipated by Hainfeld (6,645,464).

Hainfeld teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery taught by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims). The reference meets the requirements of instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu or Schlossmann or Waldrep or Hainfeld cited above.

The teachings of Hsu, Waldrep and Schlossmann have been discussed above. It is unclear from these references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming that the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts of the phospholipids to form required population of liposomes and suspend them in a suitable amount of vehicle. Since the amounts of the active agent depend upon the condition to be treated, this parameter is deemed to be a variable parameter.

Applicant's arguments have been fully considered, but are not persuasive.

Applicant argues the following:

"According to the Action, "[i]t is unclear from these [prior art] references whether the compositions contain claimed amounts of vehicle, vesicle forming component and the payload. Assuming the amounts are different, it is deemed obvious to one of ordinary skill in the art to use desired amounts." (Action, p. 7). This is an insufficient analysis on which to reject claim 16 under prevailing case law. The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, "[a]ll claim limitations must be considered" because "all words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385. With regard to claim 16, the Office Action fails to determine the exact scope and content of the cited prior art and the differences between the cited prior art and the claimed subject matter. Rather, the Action finds it "unclear" whether the elements of the claimed composition is taught by the prior art. (Action, p. 7). Nevertheless, the Action, without supporting evidence, makes the conclusory statement that the claimed composition would be obvious."

These arguments are not persuasive. Instant claims are composition claims and the examiner has already addressed the issue of jettability of the prior art compositions. The motivation to change the amounts of the ingredients need not be the same as applicants in composition claims. Therefore, the rejection is maintained.

12. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu, Schlossmann, Waldrep, Wallach (5,160,669) or Hainfeld cited above in view of Handjani (4,608,211).

The teachings of Hsu, Schlossmann, Waldrep, Wallach (5,160,669) or Hainfeld have been discussed above. What is lacking in these references is the inclusion of antifoaming agents. Such an inclusion however, with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since the reference of Handjani shows the routine practice of adding an antifoaming agent in liposomal compositions (col. 4, lines 1-15).

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that neither Wallach nor Handjani teach or suggest a composition with an antifoaming agent that is effective to prevent foaming of the solution and that Handjani actually teaches that the anti-foaming agent is introduced into the aqueous phase to be encapsulated. This argument is not persuasive. First of all, it is common knowledge that an anti-foaming agent is used to prevent foaming and therefore, if there is a surfactant in the composition or the composition has foaming properties one should be using an anti-foaming agent. Proteins taught by Handjani are surfactants and therefore, he teaches the use of anti-foaming agents. Secondly, a close examination of

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the examples indicates that the lipids are hydrated with an aqueous solution containing glucose (active agent) and the active agent is not separated. Since such a procedure results in the presence of glucose in the aqueous interior as well as outer aqueous medium, one of ordinary skill in the art would expect similar distribution when proteins are used as drugs in the aqueous medium and therefore, one of ordinary skill in the art would inter the presence of anti-foaming agent both in the aqueous interior as well as the in the outer aqueous medium in which the liposomes are suspended.

13. Claims 66-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach (5,160,669) cited above in view of Schlossmann (4,976,964).

The teachings of Wallach have been discussed above. What is lacking in Wallach is the inclusion of rheology adjusting agent and pH adjusting agents. Such an inclusion however, with a reasonable expectation of success would have been obvious to one of ordinary skill in the art since the reference of Schlossmann shows the routine practice of adding buffers and glycerol in liposomal compositions (col. 3, line 27 through col. 4, line 66).

Applicant argues that the rejection refers to Handjani and that there is no teaching of buffers and glycerol in Handjani. The examiner points out that the rejection is made over the combination of Wallach and Schlossmann and the examiner inadvertently referred to Handjani instead of Schlossmann.

14. Claims 1-3, 5, 7, 10-16 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hainfeld (6,645,464).

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Hainfeld as pointed out above teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery suggested by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims). Although Hainfeld discusses the liposomal formulations, he does not teach how to prepare the liposomal compositions to be delivered through ink jet delivery. However, since liposomal preparations, both unilamellar and multilamellar, are well known in the art, it would have been obvious to prepare them by art known techniques to be used in ink jet delivery systems. Since phospholipids are routinely used in the preparation of liposomes, selecting the specific phospholipids such as phosphatidylcholine and phosphatidylethanolamine is deemed to be within the skill of the art.

15. Claims 1, 3-5, 7-16 and 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gore (5,911,816) in view of Hainfeld (6,645,464) or Schlossmann cited above by themselves or in combination or vice versa (Schlossmann or Hainfeld individually or in combination in view of Gore).

Gore discloses liposomal compositions containing the claimed ingredients and additives as jettable solutions to be used with ink jets (abstract, columns 2-5, examples and claims). Gore does not however, teach the incorporation of biologically active agent to be used in the inkjet delivery device.

Hainfeld as pointed out above teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies,

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peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery suggested by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims).

The teachings of Schlossmann have been discussed above.

To include a pharmaceutical payload in the jettable compositions of Gore would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the references of Hainfeld and Schlossmann teach that the vesicular compositions containing drugs can be prepared and Hainfeld in particular teaches that liposomes can be loaded with pharmaceutical agents to be delivered by inkjet devices. Alternately to prepare specific liposomal compositions containing phospholipids with the additional buffers, biocides and others in the generic teachings of 'vesicles' or 'liposomes' taught by Hainfeld would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Gore teaches that such solutions are jettable using ink jet devices. The criticality of specific active agents is not readily apparent since the nature of the active agent depends upon the disease to be treated.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3-5, 7-16 and 63-67 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,911,816 (Gore) in view of Hainfeld (6,645,464).

The claims in 816 and instant claims are drawn to same compositions; the only difference is the encapsulation of pharmaceutical payload. Claims in 816 do not recite any pharmaceutical payload.

Hainfeld as pointed out above teaches liposomal and erythrocyte membrane vesicular compositions containing metal particles which in turn attached to antibodies, peptides, nucleic acids (pharmaceutical payload). The solutions contain buffer. One of the modes of delivery suggested by Hainfeld is inkjet delivery (abstract, col. 10 lines 35-67; col. 11, lines 32-59; col. 14, line 21 through col. 16, line 3; claims).

To include a pharmaceutical payload in the jettable compositions of 816 would have been obvious to one of ordinary skill in the art with a reasonable expectation of success since the reference of Hainfeld teaches that liposomes can be loaded with pharmaceutical agents to be delivered by inkjet devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

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(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore/
Primary Examiner, Art Unit 1612

GSK